

DEPARTMENT OF THE AIR FORCE 59TH MEDICAL WING (AETC) JOINT BASE SAN ANTONIO - LACKLAND TEXAS

3 MAR 2017

MEMORANDUM FOR SGVU

ATTN: COL LINDA STEEL-GOODWIN

FROM: 59 MDW/SGVU

SUBJECT: Professional Presentation Approval

- Your paper, entitled 59th Clinical Research Division, CIRT Presentation presented at/published to Clinical Investigation Research Training Meeting, 30 March 2017, BAMC, San Antonio, TX in accordance with MDWI 41-108, has been approved and assigned local file #17115.
- 2. Pertinent biographic information (name of author(s), title, etc.) has been entered into our computer file. Please advise us (by phone or mail) that your presentation was given. At that time, we will need the date (month, day and year) along with the location of your presentation. It is important to update this information so that we can provide quality support for you, your department, and the Medical Center commander. This information is used to document the scholarly activities of our professional staff and students, which is an essential component of Wilford Hall Ambulatory Surgical Center (WHASC) internship and residency programs.
- 3. Please know that if you are a Graduate Health Sciences Education student and your department has told you they cannot fund your publication, the 59th Clinical Research Division may pay for your basic journal publishing charges (to include costs for tables and black and white photos). We cannot pay for reprints. If you are 59 MDW staff member, we can forward your request for funds to the designated wing POC.
- 4. Congratulations, and thank you for your efforts and time. Your contributions are vital to the medical mission. We look forward to assisting you in your future publication/presentation efforts.

LINDA STEEL-GOODWIN, Col, USAF, BSC

Director, Clinical Investigations & Research Support

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS

INSTRUCTIONS

USE ONLY THE MOST CURRENT 59 MDW FORM 3039 LOCATED ON AF E-PUBLISHING

- 1. The author must complete page two of this form:
 - a. In Section 2, add the funding source for your study [e.g., 59 MDW CRD Graduate Health Sciences Education (GHSE) (SG5 O&M); SG5 R&D;
 Tri-Service Nursing Research Program (TSNRP); Defense Medical Research & Development Program (DMRDP); NIH; Congressionally Directed
 Medical Research Program (CDMRP); Grants; etc.]
 - b. In Section 2, there may be funding available for journal costs, if your department is not paying for figures, tables or photographs for your publication. Please state "YES" or "NO" in Section 2 of the form, if you need publication funding support.
- 2. Print your name, rank/grade, sign and date the form in the author's signature block or use an electronic signature.
- 3. Attach a copy of the 59 MDW IRB or IACUC approval letter for the research related study. If this is a technical publication/presentation, state the type (e.g. case report, QA/QI study, program evaluation study, informational report/briefing, etc.) in the "Protocol Title" box.
- 4. Attach a copy of your abstract, paper, poster and other supporting documentation.
- Save and forward, via email, the processing form and all supporting documentation to your unit commander, program director or immediate supervisor for review/approval.
- 6. On page 2, have either your unit commander, program director or immediate supervisor:
 - a. Print their name, rank/grade, title; sign and date the form in the approving authority's signature block or use an electronic signature.
- 7. Submit your completed form and all supporting documentation to the CRD for processing (59crdpubspres@us.af.mil). This should be accomplished no later than 30 days before final clearance is required to publish/present your materials. If you have any questions or concerns, please contact the 59 CRD/Publications and Presentations Section at 292-7141 for assistance.
- 8. The 59 CRD/Publications and Presentations Section will route the request form to clinical investigations, 502 ISG/JAC (Ethics Review) and Public Affairs (59 MDW/PA) for review and then forward you a final letter of approval or disapproval.
- Once your manuscript, poster or presentation has been approved for a one-time public release, you may proceed with your publication or presentation submission activities, as stated on this form. Note: For each new release of medical research or technical information as a publication/presentation, a new 59 MDW Form 3039 must be submitted for review and approval.
- 10. If your manuscript is accepted for scientific publication, please contact the 59 CRD/Publications and Presentations Section at 292-7141. This information is reported to the 59 MDW/CC. All medical research or technical information publications/presentations must be reported to the Defense Technical Information Center (DITC). See 59 MDWI 41-108, Presentation and Publication of Medical and Technical Papers, for additional information.
- 11. The Joint Ethics Regulation (JER) DoD 5500.07-R, Standards of Conduct, provides standards of ethical conduct for all DoD personnel and their interactions with other non-DoD entities, organizations, societies, conferences, etc. Part of the Form 3039 review and approval process includes a legal ethics review to address any potential conflicts related to DoD personnel participating in non-DoD sponsored conferences, professional meetings, publication/presentation disclosures to domestic and foreign audiences, DoD personnel accepting non-DoD contributions, awards, honoraria, gifts, etc. The specific circumstances for your presentation will determine whether a legal review is necessary. If you (as the author) or your supervisor check "NO" in block 17 of the Form 3039, your research or technical documents will not be forwarded to the 502 ISG/JAC legal office for an ethics review. To assist you in making this decision about whether to request a legal review, the following examples are provided as a guideline:

For presentations before professional societies and like organizations, the 59 MDW Public Affairs Office (PAO) will provide the needed review to ensure proper disclaimers are included and the subject matter of the presentation does not create any cause for DoD concern.

If the sponsor of a conference or meeting is a DoD entity, an ethics review of your presentation is not required, since the DoD entity is responsible to obtain all approvals for the event.

If the sponsor of a conference or meeting is a non-DoD commercial entity or an entity seeking to do business with the government, then your presentation should have an ethics review.

If your travel is being paid for (in whole or in part) by a non-Federal entity (someone other than the government), a legal ethics review is needed. These requests for legal review should come through the 59 MDW Gifts and Grants Office to 502 ISG/JAC.

If you are receiving an honorarium or payment for speaking, a legal ethics review is required.

If you (as the author) or your supervisor check "YES" in block 17 of the Form 3039, your research or technical documents will be forwarded simultaneously to the 502 ISG/JAC legal office and PAO for review to help reduce turn-around time. If you have any questions regarding legal reviews, please contact the legal office at (210) 671-5795/3365, DSN 473.

NOTE: All abstracts, papers, posters, etc., should contain the following disclaimer statement:

"The views expressed are those of the [author(s)] [presenter(s)] and do not reflect the official views or policy of the Department of Defense or its Components"

NOTE: All abstracts, papers, posters, etc., should contain the following disclaimer statement for research involving humans:

"The voluntary, fully informed consent of the subjects used in this research was obtained as required by 32 CFR 219 and DODI 3216.02_AFI 40-402."

NOTE: All abstracts, papers, posters, etc., should contain the following disclaimer statement for research involving animals, as required by AFMAN

"The experiments reported herein were conducted according to the principles set forth in the National Institute of Health Publication No. 80-23, Guide for the Care and Use of Laboratory Animals and the Animal Welfare Act of 1966, as amended."

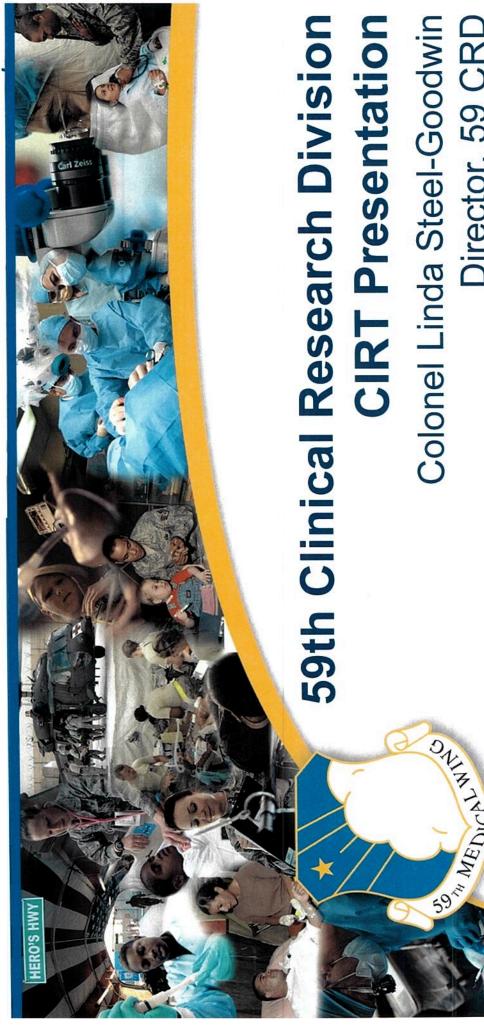
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59th Medical Wing





30 Mar 2017 Director, 59 CRD



Disclaimer



Warrior Medics – Mission Ready – Patient Focused

The views expressed are those of the author and do not reflect the official views or policy of the Department of Defense or its Components





Agenda



Warrior Medics – Mission Ready – Patient Focused

- Overview & Staff Expertise
- CIP Research Funding
- IRB/IACUC Research Subjects Protection
- Research Compliance
- GME/GHSE Animal Research & Training
- Surgical and Pathology Capabilities
- AAALAC "Emeritus" Internationally-Accredited Vivarium
- Laboratory Capabilities
- Research Statistical Support
- Research Publications/Presentations Clearance
- Website
- Points of Contact



CRD Overview



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The 59 CRD provides centralized admin, technical, logistical, statistical, researchers in the development, performance, and dissemination of and scientific support and regulatory oversight and guidance to clinical investigations.

requirements for residents, fellows, nurses, allied healthcare CRD directly supports wing readiness and certification training professionals, and providers.

Four Focus Areas:

- . Clinical Investigation Support
- 2. Training
- Support of RDT&E protocols
- 4. Research Subject Protection
- Human Subjects: IRB Institutional Review Board
- Animal Subjects: IACUC Institutional Animal Care and Use Committee



CRD Staff Expertise



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- Medicine; Certified by American College of Veterinary Pathology 1 - DVM, Board Certified American College of Lab Animal
- by Aerospace Medical Assoc; Certified in Hyperbaric Physiology 1 - PhD, Physiology/Biochem - Clinical Research Admin; Certified
- 1 ScD, Biostatistics/Epidemiology Animal Research Admin
- 2 PhD, Molecular Biology/Virology
- 1 PhD, Chemistry
- 1 PhD, Biochemistry
- 1 PhD, Biology/Neurology
- 1 DrPH, Public Health in Disease/Immunology/Occu. Health
- 1 DHSc, Health Science; Licensed Physician Assistant
- 10 Masters Degrees in various disciplines



IRB / IACUC



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PROTECTION OF HUMAN RESEARCH SUBJECTS - IRB

- Primary AFMS IRB Support over 40 sites (CONUS & OCONUS)
- Review, modify, approve/disapprove human research protocols
- Ensure training for all personnel involved in human research
- Observe/verify protocol changes
- Suspend or terminate approval

PROTECTION OF ANIMAL RESEARCH SUBJECTS - IACUC

- Set animal use policy
- Review, modify, approve/disapprove animal use protocols
- Ensure training for all personnel working with animals
- Establish Policies for use of Clinical Research Division Facility



Research Compliance



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POST-APPROVAL MONITORING (PAM)

- Improves the quality, efficiency, and effectiveness of the 59 MDW Human Research Protection Program (HRPP)
- Maximizes safety of research participants; ensures data integrity
- Confirms that research is implemented in accordance with IRBapproved protocols and applicable regulations/policies
- Provides education/tools to researchers to reduce institutional risk
- Review of study records, data storage, and security processes



GME / GHSE Animal Research and Training



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SURGICAL CAPABILITIES

- Three operating room suites:
- General and Vascular Surgery
- Orthopedic
- Ophthalmic
- Maxillofacial/Dental
- Microsurgery
- da Vinci Robotic Surgical System
- C-Arm



- Radiology/Imaging:
- ➤ Fluoroscopy ► Ultrasound
- Digital Film
- Hyperbaric/hypobaric chamber
- **Incomplete Instron Materials Testers**
- Over \$13M in medical equipment





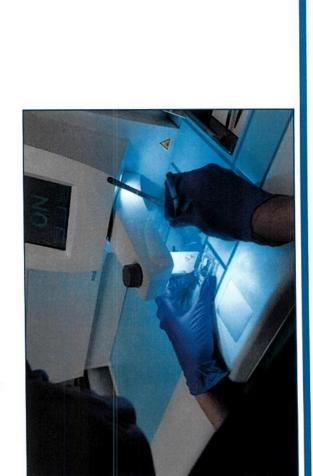
GME / GHSE Animal Research and Training



Warrior Medics – Mission Ready – Patient Focused

PATHOLOGY CAPABILITIES

- Fully equipped necropsy room
- Animal histopathology laboratory
- Gross and microscopic analyses of:
 - Y Tissues
- > Bones
 - ► Teeth
- ▶ Metal prostheses









GME / GHSE Animal Research and Training



Warrior Medics – Mission Ready – Patient Focused

AAALAC-ACCREDITED "EMERITUS" VIVARIUM

- Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC)
- Currently houses five (5) animal species for research and medical training
- 25,000 sq. ft. vivarium; 21 large animal cages, can house up to seven (7) species
- 31,000 sq. ft. of paddock area for up to 250 animals
- Animal Holding Expansion:
- ➤ Adding 10 individual cages
 - Adding a large animal run
- ➤ Adding 27 indoor holding cages







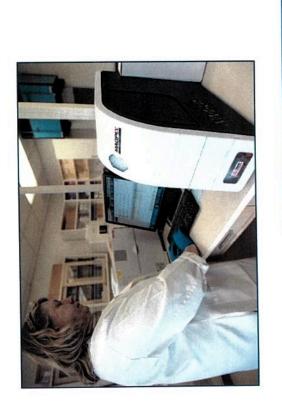
Warrior Medics – Mission Ready – Patient Focused

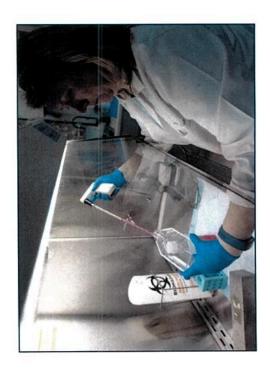
CELL BIOLOGY & IMMUNOLOGY

Equipment:

- Dedicated BSL-2 Hoods
- Flow Cytometer
- Fluorescent Microscopy
- Confocal Microscopy
- Microdialysis Analysis
- Microplate Reader
- MagPix

- **Fissue Culture**
- Proliferation-ViabilityCell Stain
- Fluorescent Microscopy/Image Analysis
- Analysis of Brain/Kidney Microdialysate Single-Plex/Multiplex Biomarker Detection/Quantification
- Cell Marker Detection/Identification









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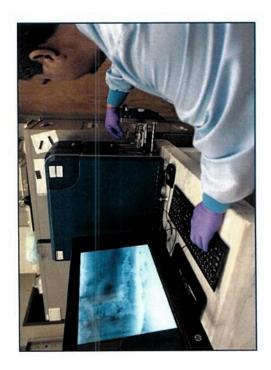
MICROBIOLOGY

Equipment:

- VITEK Bacterial ID/Susceptibility System
- Aerobic/Anaerobic Incubators
- Laminar Flow Biological Safety Cabinet
- **Bright Field Microscopy**
- Electron Microscopy

- Aerobic & Anaerobic Bacterial Cultures
- Bacterial ID and Susceptibility
- Bacterial Adhesion Studies
- Disinfectant Reliability Studies
- **Epidemiology Studies**
- Comparison of Conventional & New Clinical Microbiology Methodologies







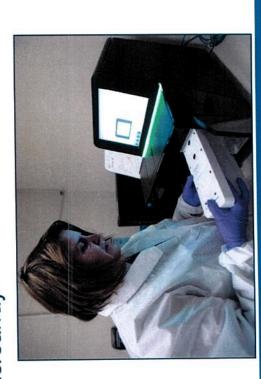


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MOLECULAR BIOLOGY

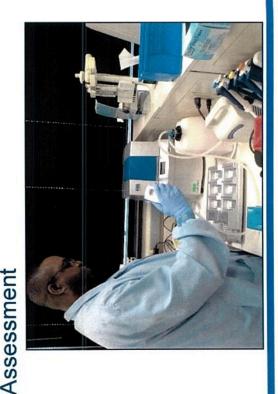
Equipment:

- Next Generation Sequencers
- NextSeq 500
- Personal Genome Machine (PGM)
- Automated Extractor
- PCR & RT-PCR
- Pyro and Sanger Sequencing
- Ultrasonicator
- Fragment Analyzer
- Microarray



- Nucleic Acid Sequencing
- ► Full Genome
- Exome
- Transcriptome
- Multiplex-Targeted
- Microbiome
- Genotyping/SNP Detection
- Nucleic Acid Fragmentation

 Nucleic Acid Quantification and Quality







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HEMATOLOGY & HEMOSTASIS

Equipment:

- CBC Analyzer (Human & Multispecies Capable)
- Coagulation Analyzers
- ▼ STA-R Evolution Hemostasis System
- Thromboelastograph Hemostasis Analyzers
- ROTEM® Delta System

- Complete Blood Count
- Platelet
- Reticulocyte
- Differential
- Routine/Specialty Coagulation Testing
 - PT/PTT/Fibrinogen
- ➤ Clotting Time, Speed of Clot Formation, Clot Firmness







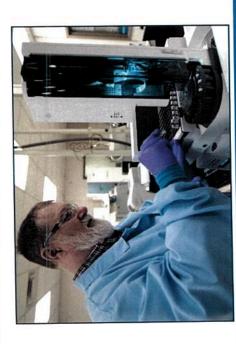


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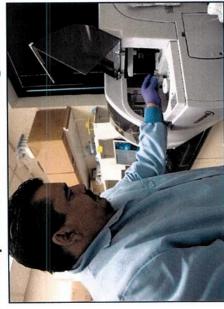
CHEMISTRY / TOXICOLOGY

Equipment:

- High/Ultra Performance Liquid Chromatography
 - ▶ Photodiode Array Detectors
 - Fluorescent Detectors
- Clinical Chemistry Analyzer
- pH/ISE/Conductivity Meter
- Three-Liquid Chromatographic Triple Quadrupole Mass Spectrometers
- **Iwo-Gas Chromatographic Mass Specs**
- Solid Phase Extraction System



- Drug and Drug Metabolites
- Natural Product Chemistry
- Disease Predictors
- Medical Readiness Research
- Full range of Clinical Chemistry analyses on Various Sample Types
- High Sensitivity pH and Ion Monitoring
- Therapeutic Drug/Immune Suppressants
- Analgesics in Pain Management
- Toxic Compounds and Allergens





Publications & Presentations



Warrior Medics – Mission Ready – Patient Focused

59 MDW FORM 3039

- Processing of Professional Medical Research/Technical Publications/Presentations (DoD Requirement)
- Enables funding source to be identified (ST requirement)
- Enables author to identify funding needs for publication

PROCESSING OF PROFESSIONAL MEDICAL RESEARCHITECHNICAL PUBLICATIONS/PRESENTATIONS	SMAL MEDICAL RE	CHINICAL	BLICATIONSFER	SENIATIONS	THOU ESSING OF TRUTESEN	SECTION MEASUREMENT OF THE COUNTY	PROCESSING OF PROFESSIONS MELICIAL MELICIPATION CONTROLL	
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CRD Website



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Clinical Research Division

59th Medical Wing

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ANNOUNCEMENT: Please send all protocol submissions to the Office of Research Protocol Support at: usaf.jbsa.59-mdw.mbx.wing-crd-protocol@mail.mil

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CRD Activities Report - FY2015 to FY2016

https://kx2.afms.mil/kj/kx8/ClinicalResearchJBSALackland/Pages/home.aspx



59 CRD Points of Contact



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Questions/Comments



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Thank You

